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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/054,354
Filing Date: January 22, 2002
Appellant(s): LAWTON ET AL.

Robert Lawton, et al.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 25, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Claims on Appeal

The Appeal involves claims 1-8.

(5) Status of Amendments After Final

Appellant's statement that no amendments were presented after final is correct.

(6) Summary of Invention

The summary of invention contained in the brief is correct.

(7) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows:

Claims 1-8 are unpatentable under 35 U.S.C. 112, first paragraph (written description).

Claims 1-8 are unpatentable under 35 U.S.C. 112, first paragraph (enablement).

Claims 1-3 are unpatentable under 35 U.S.C. 102(a).

Claims 1-6 are unpatentable under 35 U.S.C. 103(a).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Waner, T. et al, *Journal of Veterinary Diagnostic Investigation, Comparison of a Clinic-based ELISA test kit with the Immunofluoresence test for the Assay or Ehrlichia canis antibodies in Dogs*, Vol.12, (2000), pp.240-244.

WO 99/13720, 03/1999, Rikihisa et al.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

I. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. *This is a written description rejection.*

The specification broadly describes as a part of the invention a composition and an article of manufacture comprising the isolated polypeptide of SEQ ID No: 1 and variants thereof. The specification states that "variants in which amino acids of the polypeptides of the invention are substituted, deleted or added in any combination are contemplated by the invention". The specification also states " that naturally occurring variants and non-naturally occurring variants are included in the invention and may be produced by mutagenesis techniques or by direct synthesis" (page 7). Applicant has broadly described the invention as embracing any substitution, insertion or deletion change of amino acids throughout the length of the polypeptide sequence. Variants of SEQ ID No:1 correspond to sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a variant degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 U.S.C. 112, first, paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable

clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO:1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptide regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Therefore, only SEQ ID NO: 1 but not the full breadth of the claim (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

II. Claims 1-8 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition of matter and an article of manufacture that comprises an isolated polypeptide shown in SEQ ID No:1, does not reasonably provide enablement for a composition or an article of manufacture that comprises variants of SEQ ID. No:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1-8 are directed to a composition of matter and an article of manufacture comprising the isolated polypeptides of SEQ ID NO: 1 and variants thereof.

The specification is enabling only for the polypeptides of SEQ ID NO:1 as disclosed in the specification. The specification states that "variants in which amino acids of the polypeptides of the invention are substituted, deleted or added in any combination are contemplated by the invention". The specification also states " that naturally occurring variants and non-naturally occurring variants are included in the invention and may be produced by mutagenesis techniques or by direct synthesis" (page 7). The specification teaches that there are many tolerable and conservative amino acid substitutions which can be made that are not critical to protein function (pages 7-9). There is no guidance provided as to which amino acids can be added, deleted or substituted and the polypeptide would retain its biological function. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly

encompassed by the claims and the claims broadly encompass a significant number of inoperative species. Since the amino acid sequence of the polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar activity/utility requires a knowledge with regard to which amino acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved (i.e. expected intolerant to modification) and detailed knowledge of the ways in which the polypeptide's structure relates to function. However, the problem of the prediction of polypeptide structure from mere sequence data of a single polypeptide and in turn utilizing predicted structural determinations to ascertain functional aspects of the polypeptide and finally what changes can be tolerated with respect thereto is extremely complex and outside of the realm of routine experimentation.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen multiple substitutions or multiple modifications of other types and the positions within the polypeptide's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any polypeptide and the result of such modifications is unpredictable based on the instant disclosure. One skilled in the art would expect any tolerance to modifications, e.g., multiple substitutions. The sequence of some polypeptides is highly conserved and one skilled in the art would not expect tolerance to any amino acid modification in such polypeptides.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to selecting other antigens having claimed functional features, 3) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level). One of skill in the art would require guidance, in order to make or use polypeptides that are variants of SEQ ID NO: 1 in a manner reasonable in correlation with the scope of the claims. Without proper guidance, the experimentation is undue.

III. Claims 1-3 are rejected under 35 U.S.C. 102(a) as anticipated by Rikihisia et al *(WO 99/13720, 03/1999).*

Claims 1-3 are drawn to a composition of matter comprising an isolated consisting essentially of SEQ ID NO:1 and amino acid substitution variants thereof that specifically bind to an anti-*Ehrlichia* antibody.

Rikihisa et al teach diagnostic tools for veterinary and human use which are used for serodiagnosing ehrlichiosis in mammals (see the Abstract). Rikihisa et al teach compositions of matter and articles of manufacture which such as a column, plastic dish, matrix or membrane preferably nitrocellulose containing an isolated outer membrane of *E. chaffeensis or E. canis.* used in a diagnostic method of detecting antibodies to the *E. chaffeensis or E. canis* in a sample of bodily fluid from a patient (page 11). Which meets the claim limitation that "the article of manufacture comprises packaging material and contained within the packaging material the polypeptide shown in SEQ ID NO:1". Rikihisa et al teach the isolated polypeptide shown in SEQ ID NO:1, (see Figure 21B). Therefore, the composition of matter and article of manufacture of Rikihisa et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's device with the device of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the device of the prior art does not possess the same material structural and functional characteristics of the claimed device). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

IV. Claims 1-6 are rejected under 35 U.S.C. 103(a) as unpatentable over Rikihisa et al *(WO 99/13720 published March 25, 1999)* in view of *Waner et al (J Ve. Diagn Invest. 12:240-244, 2000).*

Claims 1-6 are drawn to a composition of matter and an article of manufacture comprising an isolated polypeptide shown in SEQ ID No:1 or variants thereof wherein the article of manufacture comprises a label that indicates that the polypeptide can be used for the identification of *Ehrlichia* infection in a mammal.

Rikihisa et al teach diagnostic tools for veterinary and human use which are used for serodiagnosing ehrlichiosis in mammals (see the Abstract). Rikihisa et al teach compositions of matter and articles of manufacture which such as a column, plastic dish, matrix or membrane preferably nitrocellulose containing an isolated outer membrane proteins of *E. chaffeensis or E. canis.* used in a diagnostic method of detecting antibodies to the *E. chaffeensis or E. canis* in a sample of bodily fluid from a patient (page 11). Rikihisa et al teach the isolated polypeptide shown in SEQ ID NO:1, (see Figure 21B).

Rikihisa et al do not teach the use of a label indicates that the polypeptide can be used for the identification of *Ehrlichia* infection in a mammal.

Waner et al teaches a label that indicates the use of the composition of matter or the article of manufacture (page 241, Figure 1).

It would be *prima facie* obvious at the time the invention was made to add label as taught by Waner et al to the composition of matter or article of manufacture of

Rikihisa et al because it is well known in the art to include packing material and a label to indicate the intended use of the composition of matter or article of manufacture.

The printed matter on a label or package insert does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert and the product, composition of matter or article of manufacture. See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of In re Haller, it is stated that: Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned...In accordance with the patent statutes, an article or composition of matter, in order to patentable, must not only be useful and involve invention, but must also be *new*. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statues make no provision for patenting of an article or composition which is not, in and of itself, new.

Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC)217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable

distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles. The polypeptides of the claimed articles remain fully functional absent the labeling or printed instructions for use.

It is further noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a).

Thus the instructions for use included in composition of matter and article of manufacture constitute an "intended use" for that composition of matter or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963)

In the instant case, the claims are drawn to a composition of matter and an article of manufacture which comprises an isolated polypeptide shown in SEQ ID NO:1, and a label that indicates the use of the composition of matter or article of manufacture.

The intended use which is recited on the label or package insert lacks a function relationship to the polypeptide because the insert or label does not physically or chemically affect the chemical nature of the polypeptide within the composition of matter or article of manufacture, and furthermore, the polypeptide can still be used by the skilled artisan for other purposes. Therefore the polypeptide which are comprised within the composition of matter and the article of manufacture are unpatentable over the prior art polypeptide, because they function equally effectively with or without the labeling, and accordingly *no functional relationship exists between the instructions for use and the polypeptide.*

Thus the claims are addressed as being drawn to a composition of matter and an article of manufacture comprising an polypeptide and a label that indicates that the polypeptide can be used for the identification of *Ehrlichia* infection in a mammal, the instructions on the label bearing no patentable weight with regard to double patenting, 102, and 103 rejections.

(11) Response to Arguments

Response to Arguments Traversing the Rejection of claims 1-8 under 35 U.S.C.112, first paragraph (written description).

Appellant urges that written description requires that one skilled in the art must recognize that the Appellant was in possession of the claimed genus, that is, variants of SEQ ID NO:1. Appellant refers to the Guidelines for Examination of Patent Applications under 35 U.S.C. 112, 66 Fed. Reg. 1099, 1106 (2001). Appellant urges that the

description of a representative number of species does not require the description to be such specificity that it would provide individual support for each species that the genus embraces. Appellant urges that one species can adequately support a genus. Appellant urges that distinguishing characteristics of a claimed genus include A) partial structure, B) physical and/or chemical properties, C) functional characteristics, D) known or disclosed correlation between structure and function, E) method of making and F) combinations of A-E. Appellant urges that the partial structure of the claimed variants are known, i.e. sequences having at least 85 % identity to SEQ ID NO:1 and therefore the variants have about 17 amino acids in common with the 20 amino acid long sequence as set forth in SEQ ID NO:1. Appellant urges that the specification teaches that amino acid substitution variants of the invention can be made. Appellant urges that the specification provides detailed guidance on how to construct variants of SEQ ID NO:1. Appellant urges that the partial structure of the claimed variants are known, (i.e. sequence that have at least 85% identity to SEQ ID NO:1) and therefore, the variants have about 17 amino acids in common with the 20 amino acid long sequence as set forth in SEQ ID NO:1. Appellant asserts that Table 1 demonstrates that positions 3, 8, and 13 of SEQ ID NO:1 are highly conserved across the seven sequences and positions 1,4, 5, 6, 7, 9, 10, 11, 12 and 15 are partially conserved across the 7 sequences that is only 2 different amino acids appear in these positions. Appellant asserts that only K or N appear as amino acids in position 1 across the seven sequences and one of skill in the art would recognize that variants should likely retain the amino acids at positions 3, 8 and 13 and that one of two amino acids should likely

be present at positions 1, 4, 5, 6, 7, 9, 10, 11, 12 and 15. Appellant urges that physical properties and functional characteristics of the variants are known. Appellant urges that the specification teaches that the polypeptides of the invention "specifically bind to anti-*Ehrlichia* antibodies".

The claims are drawn to compositions of matter and articles of manufacture comprising an isolated polypeptide consisting essentially of SEQ ID NO:1 and amino acid substitution variants thereof that specifically bind to an anti-*Ehrlichia* antibody. The Examiner is interpreting the compositions of matter and articles of manufacture to comprise an isolated polypeptide that bind anti-*Ehrlichia* antibody. The claims read on isolated proteins and are not limited to the amino acid sequences (SEQ ID NO: 1-7) shown in Table 1 (page 10 of Brief on Appeal). It is the Examiner's position that there is nothing on the record to show that the specification provides adequate written description for the full scope of the claims and therefore does not meet the written description requirement as set forth in 35 U.S.C. 112, first paragraph. The specification proposes to discover other members of the genus by using a sequence comparison algorithm (pages 6-7). The specification states " that naturally occurring variants and non-naturally occurring variants are include in the invention and may be produced by mutagenesis techniques or by direct synthesis" and the specification states that "variants in which amino acids of polypeptides of the invention are substituted, deleted, added in any combination are contemplated by the invention" (page 7). The specification discloses only SEQ ID NO:1 which corresponds to an isolated polypeptide of *Ehrlichia*. The specification does not provide adequate written description for the full

scope of the claimed invention. Appellant has provided no structural description accompanying the variant language (i.e. "substitution variants") recited in the claims. To address Appellant's assertions regarding, for example, substitutions at position one of SEQ ID NO:1, it should be noted that K or N, correspond to amino acids lysine and asparagine, respectively. It should also be noted that lysine is a basic amino acid and asparagine is a neutral-polar amino acid. Therefore, other basic amino acids such as arginine or histidine could be substituted for lysine at position one in the amino acid sequence as set forth in SEQ ID NO:1 and other neutral-polar amino acids such as serine, threonine, tyrosine, tryptophan, glutamine or cysteine could be substituted for asparagine at position one in the amino acid sequence as set forth in SEQ ID NO:1 to produce amino acid substitution variants. Moreover, any of the known 20 amino acids could be substituted in position one or any other position along the amino acid sequence as set forth in SEQ ID NO:1 to produce substitution variants which would have to be tested to determined if the variant retains the recited function of binding anti-*Ehrlichia* antibodies. Undue experimentation would be required to select amino acid substitution variants that retained the recite function due to variable number of modifications that can be made within the amino acid sequence as set forth in SEQ ID NO:1. While use of BLAST and other sequence comparison tools are known, it is not routine in the art to screen for multiple substitutions or multiple modifications of other types and the positions within the polypeptide's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any protein and the result of such modifications is unpredictable

based on the instant disclosure. The claims broadly encompass sequences from other species, mutated sequences, splice variants, sequences that have a recited degree of identity (similarity, homology), and so forth. One skilled in the art would concluded that Appellant was not in possession of the claimed genus polypeptides by the information disclosed in the specification without undue experimentation. The general knowledge of the art concerning species does not provide any indication of how the structure of a limited number of other species is representative of unknown species. Appellant was not in possession of the claimed genus of polypeptides at the time of filing.

Response to Arguments Traversing the Rejection of claims 1-8 under 35 U.S.C.112, first paragraph (enablement).

Appellant urges that a structural description of the claimed variants is provided by the specification. Appellant urges that variants are amino acid substitution variants that have at least 85 % identity to SEQ ID NO:1 and specifically bind an anti-*Ehrlichia* antibody. Appellant urges that the partial structure of the claimed variants are known, i.e. sequences having at least 85 % identity to SEQ ID NO:1 and therefore the variants have about 17 amino acids in come with the 20 amino acid log SEQ ID NO:1 and specifically bind an anti-*Ehrlichia* antibody. Appellant asserts that Table 1 demonstrates that positions 3, 8, and 13 of SEQ ID NO:1 are highly conserved across the seven sequences and positions 1,4, 5, 6, 7, 9, 10, 11, 12 and 15 are partially conserved across the 7 sequences that is only 2 different amino acids appear in these positions. Appellant asserts that only K or N appear as amino acids in position 1 across the seven

sequences and one of skill in the art would recognize that variants should likely retain the amino acids at positions 3, 8 and 13 and that one of two amino acids should likely be present at positions 1, 4, 5, 6, 7, 9, 10, 11, 12 and 15. Appellant refers to Table 1 and urges that the specification provides structural guidance as to which amino acids can be changed and the variant polypeptides retain their biological function. Appellant urges that the standard for enablement is whether one reasonable skilled in the art could make and use the invention for the disclosures in the patent coupled with information known in the art without undue experimentation. Appellant urges that the claims are enabled by the instant specification.

As stated above, The Examiner is interpreting the compositions of matter and articles of manufacture to comprise an isolated polypeptide that bind anti-*Ehrlichia* antibody. The claims read on isolated proteins and are not limited to the amino acid sequences (SEQ ID NO: 1-7) shown in Table 1 (page 10 of Brief on Appeal).
It is the Examiner's position that Appellant has not shown enablement for variants of SEQ ID NO:1. The specification proposes to discover other members of the genus by using a sequence comparison algorithm (pages 6-7). The specification also states " that naturally occurring variants and non-naturally occurring variants are include in the invention and may be produced by mutagenesis techniques or by direct synthesis" (page 7). The specification fails to provide guidance as to which amino acids can be changed and the polypeptides still retain their claimed biological function. In the present state of the art, the structure of a limited number of species does not provide guidance to the structure of others and is insufficient to support the claimed invention. To

address Appellant's comment regarding the requirements as set forth under 35 U.S.C. 112, first paragraph, it should be noted that the 35 U.S.C. 112 first paragraph requires that Appellant teach how to "make and use" the claimed invention not how to "find" variants of SEQ ID NO:1 that specifically bind to an anti-*Ehrlichia* antibody". A structural description is required. To address Appellant's assertions regarding, for example, substitution of amino acids at position one of SEQ ID NO:1, it should be noted that K or N, correspond to amino acids lysine and asparagine, respectively. It should also be noted that lysine is a basic amino acid and asparagine is a neutral-polar amino acid. Therefore, other basic amino acids such as arginine or histidine could be substituted for lysine at position one in the amino acid sequence as set forth in SEQ ID NO:1 and other neutral-polar amino acids such as serine, threonine, tyrosine, tryptophan, glutamine or cysteine could be substituted for asparagine at position one in the amino acid sequence as set forth in SEQ ID NO:1 to produce amino acid substitution variants. Moreover, any of the 20 known amino acids could be substituted in position one or any other position along the amino acid sequence as set forth in SEQ ID NO:1 to produce substitution variants which would have to be tested to determined if the variant retains the recited function of binding anti-*Ehrlichia* antibodies. Undue experimentation would be required to select amino acid substitution variants that retained the recite function due to variable number of modifications that can be made within the amino acid sequence as set forth in SEQ ID NO:1. While use of BLAST and other sequence comparison tools are known, it is not routine in the art to screen for multiple substitutions or multiple modifications of other types and the positions within the

polypeptide's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any protein and the result of such modifications is unpredictable based on the instant disclosure. The claims broadly encompass sequences from other species, mutated sequences, splice variants, sequences that have a recited degree of identity (similarity, homology), and so forth. The general knowledge of the art concerning species does not provide any indication of how the structure of a limited number of other species is representative of unknown species. One skilled in the art would require guidance in order to make and use the claimed composition of matter or article of manufacture comprising amino acid substitution variants of SEQ ID NO:1 commensurate with the claims. Without such guidance the experimentation to arrive at the claimed invention would be undue.

Response to Arguments Traversing the Rejection of claims 1-3 under U.S.C.102(a) (Rikihisa et al.).

Appellant urges that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps that do not materially affect the basic and novel characteristics of the claimed invention". Appellant urges that the claims recite an *E. canis* polypeptide portions or fragments. Appellant urges that the claimed polypeptides can be used to detect the presence of anti-*Ehrlichia* antibodies and the fragments can also be used as reagents in assays that provide greater sensitivity than the reagents taught in Rikihisa. Appellant urges the proteins of the prior art (full-length proteins) would result in assays that are less sensitive than those disclosed in the

instant specification. Appellant refers to the declaration filed under 37 C.F.R. 1.132 of Dr. Chandrashekar. Appellant urges that the addition of amino acids to the claimed isolated polypeptides so they encompass the whole proteins of Rikihisa would materially affect the basic and novel characteristics of the polypeptides.

The Examiner is interpreting the claimed invention as compositions of matter and articles of manufacture that comprise an isolated polypeptide that bind anti-*Ehrlichia* antibody. The Examiner is viewing the compositions of matter and articles of manufacture to read on a solid support such well in a microtiter plate, magnetic beads, columns, membranes and the like (instant specification pages 12-13) and not a reagent inasmuch as the claims recite compositions of matter and articles of manufacture containing the polypeptides. It should be noted that "comprising" is open claim language and the transitional phrase "consisting essentially of" only refers to the isolated polypeptide as set forth in SEQ ID NO:1. Therefore, the claims read on whole proteins. While claim 6 specifies *E. canis* or *E. chaffeensis*, it is only within the context of identifying an infection. The claims do not require that the polypeptides are derived from any *Ehrlichia* species. It should be further noted that the protein of the prior art is used to detect *Ehrlichia* antibodies. Therefore, the addition of amino acids to SEQ ID NO:1 does not affect the basic and novel characteristics of the invention. It is the Examiner's position that Rikihisa et al anticipate the claimed invention because Rikihisa et al teach compositions of matter and articles of manufacture that comprise the isolated polypeptide as set forth in SEQ ID NO:1 (see Figure 21B for the sequence and page 11 for the compositions of matter and articles of manufacture as taught by the prior art). To

address Appellants comments regarding the Declaration of Dr. Chandrashekar, which is directed to issues regarding sensitivity and specificity, it should be remembered that there are no limitations in the claims requiring that the devices require any particular level of sensitivity. It is noted that the features upon which Appellant relies (i.e., sensitivity) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The Declaration of Dr. Chandrashekar does not provide a comparison of the protein of the prior art and the claimed polypeptides. Therefore, the declaration of Dr. Chandrashekar is not sufficient overcome to the instant rejection.

(Response to Arguments Traversing the Rejection of claims 1-3 under U.S.C. 103(a) (Rikihisa et al in view of Waner et al).

Appellant urges that Rikihisa et al does not teach or suggest isolated polypeptides consisting essentially of SEQ ID NO:1. Appellant urges that Waner et al do not correct the defects of the primary reference by teaching the elements missing from Rikihisa et al. Appellant urges that since the combination of references do not teach or suggest every element of the claims, they cannot render the claims obvious.

Rikihisa et al teach compositions of matter and articles of manufacture which such as a column, plastic dish, matrix or membrane preferably nitrocellulose containing an isolated outer membrane proteins of *E. chaffeensis or E. canis.* Rikihisa et al do not teach the use of a label indicates that the polypeptide can be used for the identification

of *Ehrlichia* infection in a mammal. However, Waner et al teaches a label that indicates the use of the composition of matter or the article of manufacture (page 241, Figure 1). It would be *prima facie* obvious at the time the invention was made to add label as taught by Waner et al to the composition of matter or article of manufacture of Rikihisa et al because it is well known in the art to include packing material and a label to indicate the intended use of the composition of matter or article of manufacture. It should be noted that the printed matter on a label or package insert does not lend patentable weight as a limitation of the claimed product, absent a functional relationship between the label or package insert and the product, composition of matter or article of manufacture. See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. It is the position of the Examiner that the combination of references teach the claimed invention.

Examiner's Answer Conclusion

For the above reasons, it is believed Examiner should be affirmed.

Respectfully submitted,

Vanessa L. Ford
January 6, 2005

Lynette F. Smith
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